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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,795	10/31/2003	Sabina Cauci	13581 US	1736

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EXAMINER	
GITOMER, RALPH J	
ART UNIT	**PAPER NUMBER**
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,795	CAUCI, SABINA	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-16 and 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-16 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment received 12/6/07 has been entered and claims 1-3, 5-16, 28-33 are considered here. The tables at the end of the specification should properly be presented as Figures and the specification include a Brief Description of the Drawings. There may be a typo in claim 1(b) line 1 and in claim 33 line 2. Correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-16, 28-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-8 of copending Application No. 10/470,690. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '690 also include antibodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-16, 28-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-54 of copending Application No. 10/467,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because the three elements presently claimed together are claimed separately in different combinations in '357. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The response received 12/6/07 is silent regarding the above rejections.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-16, 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Soothill, Johnson, Lawrence, Cauci, Cauci, McGregor, and Briselden.

Soothill (WO 00/55354) entitled "A Diagnostic Test" teaches on page 4 a test for sialidase activity as an indicator of BV and therefor a predictor of the likelihood of preterm birth.

Johnson (WO 00/24753) entitled "Chromogenic Substrates of Sialidase and Methods of Making and Using the Same" teaches on page 2 first paragraph, measurement of sialidase level in vaginal samples could be used to diagnose bacterial vaginosis.

Lawrence (5,571,684) entitled "Assay for Proline Iminopeptidase and Other Hydrolytic Activities" teaches in column 2 first full paragraph, vaginal pH of women with BV or trich is above 4.5, whereas the normal vaginal pH is less than 4.5. In column 7 second full paragraph, the substrate detects peptidases where the substrate residue is proline. In column 12, line 61, vaginal fluid is tested.

Cauci (Am J Obstet Gynecol) entitled "Immunoglobulin A Response Against Gardnerella vaginalis Hemolysin and Sialidase Activity in BV" teaches in the abstract, there is a correlation between sialidase activity in vaginal fluids and bacterial vaginosis.

Cauci (J of Infect Diseases) entitled "Impairment of the Mucosal Immune System" teaches on page 1698, BV is associated with preterm delivery, chorioamniotis, amniotic fluid infections, postcesarean endometritis, salpingitis, and HIV infection. On page 1701 sialidase activity correlated with BV and to a lesser extent prolidase where no prolidase activity was detected in healthy women.

McGregor (Am J Obstet Gynecol) entitled "Bacterial Vaginosis is Associated With Prematurity and Vaginal Fluid Mucinase and Sialidase" teaches in the abstract preterm birth and other adverse pregnancy outcomes are linked with infection. Sialidiases from BV are associated with vaginal microorganisms and intrauterine infection and preterm birth.

Briselden (J of Clinical Micro) entitled "Sialidases (Neuraminidases) in BV and BV Associated Microflora" teaches in the abstract, BV is associated with prematurity and upper genital tract infection. Elevated levels of sialidase activity is highly associated with BV.

The claims may differ from the above references in that they recite specific levels of sialidase and/or prolidase indicate some odds ratio value or score. Some dependent claims include a pH range determination and/or score.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to select a particular population of women at risk for pathologies by determining sialidase and/or prolidase because each of the above references teaches the same method for determining the risk of the same pathologies as claimed. Regarding the selection of some odds ratio being calculated from some level of detected sialidase and/or prolidase, no novelty is seen in such selection because each of the references show data, usually presented as a curve, where at some cutoff some degree of correlation between enzyme levels detected and pathology may be inferred. This is standard practice in clinical diagnosis. Regarding determining pH level of vaginal fluid as claimed, it is known and taught by some of the above references such as Lawrence that normal vaginal pH is below 4.5 and ranges above 4.5 are associated with BV and other pathologies.

Applicant's arguments filed 12/6/07 have been fully considered but they are not persuasive.

Applicant argues that the above cited references do not use the correlation to select a population having a risk where the claims have a cutoff value to select a population. A correlation is different from a risk factor and the claimed risk factor is novel because it suggests a probability. Regarding Soothill, an indicator of BV is not necessarily a predictor of preterm birth and Soothill does not present a comparison between healthy people and those with pathologies to determine a critical value to decide whether to treat or not. The method of Johnson uses a different method for determining sialidase than the present invention. Lawrence teaches that elevated vaginal pH is not predictive of any adverse pregnancy outcome. Cauci teaches elevated sialidase is a marker for early adverse pregnancy outcomes but not for late preterm birth. McGregor does not teach the same method as claimed, it is more directed to sialidase activity is unchanged after treatment is a risk for low birth weight. Briselden correlates the presence of sialidase with BV pathology but not the risk factor of adverse pregnancy outcome and only suggests a relationship between BV and prematurity.

It is the examiner's position that the present claims select some value based on the activity of sialidase and/or prolidase as correlated to any obstetric or gynecologic pathology risk. Many of the above points argued are not claimed. Selecting any degree of risk would be encompassed by each of the above references which also teach some correlation between sialidase and/or prolidase activity and disease. Note that BV is a gynecologic pathology.

Regarding the quantum issue of statistical risk, either a single specific woman will have a given pathology such as those listed in claim 5, or she will not. To determine probability in order to determine if treatment is warranted, is a fundamental principle of medicine. The selection of some value cutoff of each parameter determined as correlated to a particular outcome is not an invention, it is a judgment call based on the best available information. Different practitioners will make different decisions dependent upon many factors including their perception of the cost, efficacy and risks of the treatment or of further testing.

A reading of the specification reveals no specific point of novelty. Regarding the presently claimed cutoff values regarding odds ratios, no patentability is seen in claiming some particular point on a curve. No results are claimed for such cutoff values.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-16, 28-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to risk of developing obstetric or gynecologic pathologies in general. Claim 5 lists a number of pathologies including various sites of infection, STD's in general, and malignancies. It is not seen how the present invention could predict the risk of all such maladies. For example, does the invention predict the risk of a Nabothian cyst or ovarian carcinoma?

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative pathologies claimed.

2. Amount of direction or guidance presented is insufficient to predict which pathologies encompassed by the claims would work.

3. Presence of working examples are only for a single specific pathology and extension to other pathologies has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most related pathologies are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of pathologies.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 12/6/07 have been fully considered but they are not persuasive.

Applicant argues that one of skill could practice the invention and some pathologies are taught in the specification.

It is the examiner's position that the rejection is based on the specification as originally filed does not enable one to select the risk of developing any and all obstetric or gynecologic pathologies as claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ralph Gitomer
Primary Examiner
Art Unit 1657